REMARKS

Claims 1-34 are pending in the application.

Claims 10-11, 14, 23-24 and 27-34 are amended above in a manner that causes them to be patentable over the prior art.

The specification is amended above to correct errors.

No new matter has been added to the application by these specification and claim amendments.

I. THE ALLOWED AND ALLOWABLE CLAIMS

The Applicants note that claims 1-9 and 17-22 are allowed, and this is very much appreciated.

The Applicants further acknowledge that the examiner has concluded that claims 11-16, 24-26 and 32-34 are allowable and would be allowable if rewritten in independent form.

II. THE SECTION 101 REJECTION

The examiner rejected claims 27-34 under 35 U.S.C. 101 for being directed to non-statutory subject matter.

Claims 27-34 are amended above in a manner that overcomes the examiner's rejection.

III. THE ANTICIPATION REJECTION

Claims 10, 23 and 31 stand rejected under 35 U.S.C. 102(e) as being anticipated by WO 02/47032 to Vaisberg. Regarding claim 10, the Examiner states that Vaisberg discloses a method of measuring mitotic activity from histopathological specimen image data. In particular, it is the examiner's position that Vaisberg page 3, lines 7-8, discloses analyzing images of cells and categorizing the cells in particular cell cycle phases based upon certain features; page 3, lines 9-27 discloses characterize a cell as mitotic based on morphological and textual parameter such as the variance of the pixel intensities; page 12, lines 1-9, pixels with intensity values above threshold in a given neighborhood are deemed to belong to a particular cell. *(underlined phrases were omitted by the Examiner)*. The Examiner indicates that analogous arguments apply to

related claims 23 and 31. Claims 10, 23 and 31 are amended above in a manner that causes them to be clearly novel over Vaisberg.

Claims 10, 23, and 31 are novel because Vaisberg discloses a different technique to that claimed in claim 10 for the each following reasons – proof of only one of which is necessary to overcome the examiner's novelty rejection. Similar remarks apply to claims 23 and 31.

(a) Vaisberg does not use histopathological specimen image data;

(b) Vaisberg does not measure mitotic activity directly, but instead amount of DNA;

(c) Vaisberg does not use a threshold to discriminate between mitotic and non-mitotic cells, but instead to discriminate between cell (DNA) images and background;

(d) Vaisberg does not provide a mitotic count of the kind required for cancer diagnosis;

(e) Vaisberg does not use histopathological specimen staining of the kind associated with measuring mitotic activity; and

(f) Vaisberg does not use color image data, but instead monochromatic image data.

The above reasons will now be discussed in more detail. Regarding (a), Applicant's specification at page 7 lines 1-5 briefly describes the preparation of histopathological specimens from which image data is obtained for processing in accordance with Applicant's invention. In brief, in conventional histopathology, sections are cut from tissue samples and placed on slides. The slides are stained to delineate tissue and cellular structure for assessment of mitotic activity.

In contradistinction, Vaisberg discloses analyzing images of cells to categorize the cells in particular cell cycle phases. (See e.g. page 2 line 8 of Vaisberg). This is accomplished in Vaisberg by estimating the amount of DNA in a cell which is evident from the following Vaisberg teachings:

• Page 10 lines 6-8 of Vaisberg.

• Page 8 lines 26-28 of Vaisberg which states "the invention can identify the amount of DNA in a cell from its image. The invention can also determine which phase of the cell cycle that the cell was in when its image was taken".

• Page 10 lines 3-8 of Vaisberg which states "Each cell (DNA) representation obtained by segmentation is separately analyzed to extract various relevant parameters. Generally these parameters are chosen to indicate the amount of DNA in a given cell and/or the distribution of that DNA at locations within the cell".

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- Page 21 lines 16-22 and Figure 11A of Vaisberg relating to classifying cells into G1, S and G2 states from a histogram of number of cells against total amount of DNA.

A representation of a cell in terms of DNA is not conventional histopathological specimen image data, which are color images produced by staining. For at least this reason, claims 10, 23 and 31 are novel in view of Vaisberg.

Claims 10, 23 and 31 are independently novel because Vaisberg does not measure mitotic activity directly, but instead amount of DNA. The Applicant's specification at page 28 line 12 to page 29 line 22 discloses measuring mitotic activity as per claim 10. Vaisberg page 2 lines 3-4 discloses that the stage of a given cell in the cell growth and division cycle is commonly determined by measuring the quantity of DNA in the cell. (See Vaisberg at page 9 line 31 to page 10 line 2) This Vaisberg excerpt discloses that the intensity value of each pixel *(i.e. in the image)* represents the amount of DNA at the corresponding location – which is not a direct measurement of mitotic activity.

Claims 10, 23 and 31 are further independently novel because Vaisberg does not use a threshold to discriminate between mitotic and non-mitotic cells, but instead to discriminate between cell (DNA) images and background. Applicant's specification at page 28 lines 11 to 22 discloses measuring mitotic activity using thresholds as claimed. Vaisberg at page 12 lines 7-9 discloses using a threshold to discriminate between cell (DNA) images and background, not mitotic cells.

Claims 10, 23 and 31 are also independently novel because Vaisberg does not provide a mitotic count of the kind required for cancer diagnosis as claimed. Applicant's specification page 30 provides a mitotic count of the kind required for cancer diagnosis. Vaisberg has been studied throughout but no such count has been found.

Claims 10, 23 and 31 are further independently novel because Vaisberg does not disclose using histopathological specimen staining of the kind associated with measuring mitotic activity. The Applicant's specification at page 7 lines 3-5 briefly describes histopathological specimens obtained as tissue samples on slides with staining to delineate tissue and cellular structure for assessment of mitotic activity. Vaisberg does not use histopathological specimen staining of this kind. Instead Vaisberg page 11 lines 10-24 discloses cells treated to contrast the cell's DNA from other components and background. The cells are treated with an agent that binds to DNA and

shows up in an image. The agent is luminescent, radioactive, fluorescent, etc., e.g. fluorescent DNA intercalators and fluorescently labeled antibodies to DNA. Intercalating dyes are materials with a high affinity for DNA and have molecules which intercalate between (interleave with) DNA planar base pairs (Chambers Dictionary of Science and Technology 1999). Further, Vaisberg page 11 lines 27-30 discloses a collection of cells treated with a fluorescent agent being illuminated with light at a frequency which excites fluorescence. A detector is tuned to collect light at the frequency of fluorescence emission. Collected light is used to generate an image and highlight regions of high DNA concentration. So unlike conventional histopathology, Vaisberg does not use staining to produce color image data, i.e. image data in multiple colors, but instead discloses monochromatic excitation of fluorescence etc. to generate monochromatic image data by fluorescence response. This further demonstrates that Vaisberg does not use color image data, but instead monochromatic image data and claims 10, 23 and 31 are novel for this reason as well.

CONCLUSION

All pending claims are believed to be ready for patenting for the reasons recited above. Favorable reconsideration and allowance of all pending claims is, therefore, courteously solicited.

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